

REMARKS

Reconsideration of the application is respectfully requested.

I. Status of the Claims

Claims 1-3, 8 and 9 are pending in the application.

Claims 4-7 were previously canceled without prejudice or disclaimer of the subject matter contained therein.

Claim 9 has been withdrawn from examination.

Claims 1 and 8 have now been added. No new matter is added.

II. Specification

The Examiner objects to the specification as failing to provide proper antecedent basis for the claimed subject matter. The Examiner states that the specification does not teach which of the variables and equations disclosed on pages 12-30 of the specification corresponds in Claim 8 to the claimed second measurement value, the second theoretical value, the difference between the second measurement value and the second theoretical value, the adjusted blood flow rate, and the second predetermined acceptable ration difference.

It is respectfully submitted that the Specification describes performing separate sets of measurements and calculations in determining the location of abnormal behavior in the device, as recited in claim 8. A first set of measurements and calculations are performed to determine if there is a malfunction of either of the blood pump or the ultrafiltration pump. See, e.g. Specification at page 13, lines 7-16. As amended, claim 8 recites that “the blood pump is further configured to adjust the preset blood flow rate to an adjusted blood flow rate when a trouble condition exists.”

See, e.g. Specification at page 13, line 23 to page 14, line 17, particularly page 14, lines 14-15. The ultrafiltration pump is kept at a set value and a second set of measurements and calculations are performed to determine if the problem exists in the blood pump or the ultrafiltration pump. See, e.g. Specification at page 14, line 14 to page 15, line 5. Thus, Applicants respectfully request that the objection be withdrawn.

III. Rejections Under 35 U.S.C. § 103

Claims 1-3 and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,554,789 to Brugger. The Examiner states that Brugger discloses most of the features of the claimed invention and contends that the BFR, RFR, UFR and filtration fraction value FF described in Brugger can be used to evaluate operation of the blood purification device by comparing first and second measured hematocrit values. *See*, Final Office Action mailed November 4, 2008, page 6, lines 2-5. The Examiner admits that Brugger does not disclose the recited measured ratio value or theoretical value, comparing the measured and theoretical value to obtain an evaluation value, or that the evaluation unit evaluates whether the evaluation value is larger than a first predetermined acceptable ratio difference. The Examiner contends that it would have been obvious to one of ordinary skill in the art to modify Brugger to use a suitable mathematical formula to calculate theoretical values that differ enough from the measured values to determine that a trouble condition exists. Applicants respectfully traverse the rejection.

Independent claim 1 of the present application recites a calculating unit to calculate “an evaluation value used to evaluate operation of the blood purification device,” “an evaluation unit coupled to evaluate whether the evaluation value is larger than a first predetermined acceptable ratio

difference; and a reporting unit configured to report a trouble condition for at least one of said blood pump and said blood purifier when the evaluation value is larger than a predetermined value.” It is respectfully submitted that it would not have been obvious to include a reporting unit configured to report a trouble condition for at least one of a blood pump and blood purifier when an evaluation value is larger than a predetermined value in the fluid circuit assembly of Brugger.

Brugger describes pressure sensors that are used to determine the function and integrity of the pumps. *See*, Brugger, column 22, lines 47-51 and column 24, lines 35-45. Brugger does not describe the use of hematocrit values, the filtration fraction value FF or the pump rates to determine a trouble condition. Thus, Brugger describes steps for determining the function and integrity of the pumps, but these steps do not include reporting a trouble condition when an evaluation value, based on a ratio of hematocrit values and preset blood flow and water removal rates, is larger than a predetermined value, as recited in claim 1. Accordingly, Brugger does not teach or suggest reporting a trouble condition based on the recited evaluation value. Moreover, such a feature would not have been obvious to a person of ordinary skill in the art.

Brugger teaches that the filtration fraction value FF can be used to control the ultrafiltration rate. Specifically, Brugger teaches that the machine 16 includes a flow restrictor positioned to engage a region of the venous blood path and pinch the region of the blood path to alter the outlet flow of blood. *See* Brugger, column 23, lines 58-63. The machine 16 derives the fluid reduction ratio based on the pre-treatment and post-treatment hematocrit values and issues commands to the flow restrictor to bring the difference between the fluid reduction value and the desired FF to zero. Thus, Brugger teaches that variations in the FF from the desired FF are within the normal operating conditions and any variations from the desired FF should be addressed by adjusting the flow rate in

the venous path with the flow restrictor. Brugger does not teach that a variation between the derived fluid reduction ratio and the desired FF indicate a trouble condition. Accordingly, a person of ordinary skill in the art would have no reason to include a “a reporting unit configured to report a trouble condition for at least one of said blood pump and said blood purifier when the evaluation value is larger than a predetermined value,” as recited in claim 1.

With specific regard to the Examiner’s contention that “it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brugger to use a suitable mathematical formula to calculate when the theoretical values differ enough from the measured values to determine that a trouble conditions exists,” (See, Final Office Action mailed November 4, 2008, page 7, lines 16-19) it is respectfully submitted that Brugger does not teach or suggest that variations between the measured values of FF, BFR, RFR or UFR and the expected values ever indicate a trouble condition. In fact, Brugger teaches that variances between the derived FF and the desired FF can be overcome using a flow restrictor. Thus, a person of ordinary skill in the art would not expect that such variation indicates a trouble condition in either of the blood pump or the blood purifier, as recited in claim 1. Accordingly, there would be no reason to include a reporting unit configured to report a trouble condition based on this information, as a person of ordinary skill in the art would not expect that a trouble condition exists. Further, there would be no need to include a reporting unit configured to report such a trouble condition based on this information, as Brugger already includes pressure sensors which would sense and report any unwanted operating conditions in the blood pump or ultrafiltration systems. Moreover, there is no teaching in Brugger, nor is there any support in the cited references or the Office Action that a person of ordinary skill in the art would recognize when the “theoretical values differ enough from the measured values to determine

that a trouble condition exists” (emphasis added) and when the values differ enough that the flow restrictor should be adjusted, as taught by Brugger.

For all of the foregoing reasons, it is respectfully submitted that claim 1 of the present application is not obvious in view of Brugger. Thus, claim 1 cannot be rejected under 35 U.S.C. § 103(a) in view of Brugger. Claims 2, 3 and 8 depend from claim 1 and are patentable over Brugger for at least the same reasons as claim 1.

Reconsideration and withdrawal of the rejection of claims 1-3 and 8 under 35 U.S.C. § 103(a) in view of Brugger is respectfully requested.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

The Examiner is respectfully requested to contact the undersigned at the telephone number indicated below if the Examiner believes any issue can be resolved through either a Supplemental Response or an Examiner's Amendment.

Should additional fees be necessary in connection with the filing of this response, or if an additional petition for extension of time is required for timely acceptance of the same, the Commissioner is hereby authorized to charge Deposit Account No. 04-0100 for any such fees, and applicants hereby petition for any needed extension of time.

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Respectfully submitted,

By 

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